

PATENT  
Attorney Docket No. EXT-047CP

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Shuber  
SERIAL NO.: 09/988,491 GROUP NO.: 1655  
FILING DATE: November 20, 2001 EXAMINER: Not Yet Assigned  
TITLE: METHOD FOR ALTERATION DETECTION

Assistant Commissioner for Patents  
Washington, D.C. 20231

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INFORMATION DISCLOSURE STATEMENT

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Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicant hereby makes of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Pursuant to 37 C.F.R. § 1.98 (d), copies of references A1-A59; B1-B26 & C1-C112 are not provided herewith as each reference has been previously submitted or cited (with references A58-A59 cited by the Examiner) in parent application serial no. 09/809,713, which is relied upon for an earlier effective filing date under 35 U.S.C. § 120.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application, or within three (3) months of the **date of entry of the national stage** as set forth in 37 CFR 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 CFR 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 CFR 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 CFR 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**

- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 CFR 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

### STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

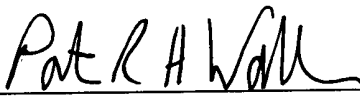
- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 CFR 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Date: February 27, 2002  
Reg. No. 41,418

Tel. No.: (617) 248-7240  
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2285670

  
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FORM PTO - 1449

## INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: EXT-047CP

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## U.S. PATENT DOCUMENTS

EXAMINER INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	4,683,195	7/28/1987	Mullis et al.		2/7/86
	A2	4,871,838	10/3/1989	Bos et al.		7/23/85
	A3	5,126,239	6/30/1992	Livak et al.		3/14/90
	A4	5,137,806	8/11/1992	LeMaistre et al.		12/11/89
	A5	5,202,231	4/13/1993	Drmanac, et al.		6/18/91
	A6	5,272,057	12/21/1993	Smulson et al.		10/14/88
	A7	5,302,509	4/12/1994	Cheeseman		2/27/91
	A8	5,330,892	7/19/1994	Vogelstein et al.		3/13/91
	A9	5,348,855	9/20/1994	Dattagupta et al.		10/4/91
	A10	5,468,613	11/21/1995	Erlich et al.		3/9/90
	A11	5,512,441	4/30/1996	Ronal		11/15/94
	A12	5,527,676	6/18/1996	Vogelstein et al.		3/22/93
	A13	5,532,108	7/2/1996	Vogelstein		4/14/94
	A14	5,571,676	11/5/1996	Shuber		6/7/95
	A15	5,578,458	11/26/1996	Caskey, et al.		10/1/91
	A16	5,582,989	12/10/1996	Caskey et al.		9/30/94
	A17	5,589,330	12/31/1996	Shuber		7/28/94
	A18	5,605,798	2/25/1997	Koster		3/17/95
	A19	5,633,134	5/27/1997	Shuber		9/19/94
	A20	5,670,325	9/23/1997	Lapidus et al.		8/14/96
	A21	5,698,400	12/16/1997	Cotton et al.		9/16/96
	A22	5,707,806	1/13/1998	Shuber		6/7/95
	A23	5,741,650	4/21/1998	Lapidus et al.		8/14/96
	A24	5,811,239	9/22/1998	Frayne		5/13/96
	A25	5,830,665	11/3/1998	Shuber et al.		3/3/97

EXAMINER

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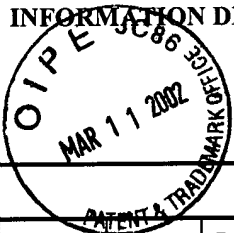
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	A26	5,834,181	11/10/1998	Shuber		9/13/96
	A27	5,849,483	12/15/1998	Shuber		6/7/95
	A28	5,882,856	3/16/1999	Shuber		6/7/95
	A29	5,888,778	3/30/1999	Shuber		6/16/97
	A30	5,888,780	3/30/1999	Dahlberg et al.		2/19/97
	A31	5,928,870	7/27/1999	Lapidus et al.		6/16/97
	A32	5,952,178	9/14/1999	Lapidus et al.		4/13/98
	A33	6,020,137	2/1/2000	Lapidus et al.		11/23/98
	A34	6,048,689	4/11/2000	Murphy et al.		3/28/97
	A35	6,074,823	6/13/2000	Koster		11/6/96
	A36	6,100,029	8/8/2000	Lapidus et al.		12/4/97
	A37	6,143,529	11/7/2000	Lapidus et al.		3/26/99
	A38	6,146,828	11/14/2000	Lapidus et al.		7/3/98
	A39	6,197,498 B1	3/6/2001	Koster		4/6/99
	A40	6,203,993 B1	3/20/2001	Shuber et al.		4/4/2000
	A41	6,207,372 B1	3/27/2001	Shuber		6/6/96 (PCT)
	A42	6,214,558 B1	4/10/2001	Shuber et al.		7/27/2000
	A43	6,221,601 B1	4/24/2001	Koster et al.		11/2/99
	A44	6,268,136 B1	7/31/2001	Shuber et al.		11/23/98
	A45	6,280,947 B1	8/28/2001	Shuber et al.		8/11/99
	A46	6,300,077 B1	10/9/2001	Shuber et al.		4/4/2000
	A47	6,303,304 B1	10/16/2001	Shuber et al.		2/2/99
	A48	5,759,777	6/2/1998	Kearney et al.		6/6/95
	A49	5,846,710	12/8/1998	Bajaj		8/6/93
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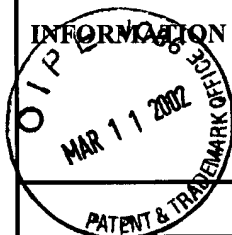
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	A50	5,888,819	3/30/1999	Goelet et al.			3/5/91
	A51	6,013,431	1/11/2000	Söderlund et al.			12/2/93
	A52	5,098,823	3/24/1992	Bodmer et al.			8/11/88 (PCT)
	A53	5,382,510	1/17/1995	Levine et al.			7/10/92
	A54	5,489,508	2/6/1996	West et al.			3/24/93
	A55	5,545,527	8/13/1996	Stevens et al.			7/8/94
	A56	5,552,283	9/3/1996	Diamandis et al.			2/14/95
	A57	5,645,986	7/8/1997	West et al.			11/12/93
	A58	6,025,127	2/15/2000	Sidransky			1/14/94
	A59	6,051,378	4/18/2000	Monforte et al.			3/4/97

## FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B1	0 332 435 A2	9/13/89	EPO			3/9/89	No	Yes
	B2	0 332 435 B1	9/13/89	EPO			3/9/89	No	Yes
	B3	0 407 789 A1	1/16/91	EPO			6/22/90	No	Yes
	B4	0 407 789 B1	1/16/91	EPO			6/22/90	No	Yes
	B5	0 408 918 A1	1/23/91	EPO			6/21/90	No	Yes
	B6	0 408 918 B1	1/23/91	EPO			6/21/90	No	Yes
	B7	0 497 527 A1	8/5/92	EPO			1/27/92	No	Yes
	B8	0 664 339 A1	7/26/95	EPO			7/7/94	No	Yes
	B9	WO 90/09455	8/23/90	PCT			2/13/90	No	Yes
	B10	WO 91/13075	9/5/91	PCT			2/15/91	No	Yes
	B11	WO 93/20233	10/14/93	PCT			3/22/93	No	Yes
	B12	WO 94/11383	5/26/94	PCT			11/8/93	No	Yes

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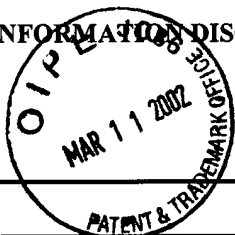
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	B13	A-11325/95	4/18/96	AU			10/5/94	No	Yes
	B14	WO 95/07361	3/16/95	PCT			9/9/94	No	No (abstract in English)
	B15	WO 95/19448	7/20/95	PCT			1/13/95	No	Yes
	B16	WO 96/13611	5/9/96	PCT			10/27/95	No	Yes
	B17	WO 97/23651	7/3/97	PCT			12/20/96	No	Yes
	B18	WO 98/38338	9/3/98	PCT			2/27/98	No	Yes
	B19	WO 98/58081	12/23/98	PCT			6/4/98	No	Yes
	B20	WO 92/15712	9/17/92	PCT			3/4/92	No	Yes
	B21	0 259 031 B1	11/9/94	EPO			8/11/87	No	Yes
	B22	0 608 004 A2	7/27/94	EPO			8/11/87	No	Yes
	B23	0 390 323 A2	10/3/90	EPO			2/20/90	No	Yes
	B24	WO 95/09928	4/13/95	PCT			9/26/94	No	Yes
	B25	WO 95/12607	5/11/95	PCT			11/2/94	No	Yes
	B26	WO 96/12821	5/2/96	PCT			10/19/95	No	Yes

## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C1	Aaltonen <i>et al.</i> (1994) "Replication Errors in Benign and Malignant Tumors from Hereditary Nonpolyposis Colorectal Cancer Patients" <u>Cancer Research</u> 54: 1645-1648
	C2	Aaltonen <i>et al.</i> (1998) "Incidence of Hereditary Nonpolyposis Colorectal Cancer and the Feasibility of Molecular Screening for the Disease" <u>The New England Journal of Medicine</u> 338: 1481-1487
	C3	Ausubel <i>et al.</i> , (1995), <u>Short Protocols in Molecular Biology</u> , 3d ed., pp. 2-3 -2-12, 3-30 -3-33.
	C4	Bertario <i>et al.</i> (1999) "Risk of Colorectal Cancer Following Colonoscopic Polypectomy" <u>Tumori</u> 85: 157-162
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## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
C5	Blum H.E., (1995) "Colorectal Cancer: Future Population Screening for Early Colorectal Cancer" <u>European Journal of Cancer</u> , Vol. 31A, pp. 1369-1372.
C6	Bos <i>et al.</i> , (May 28, 1987) "Prevalence of <i>ras</i> Gene Mutations in Human Colorectal Cancers," <u>Nature</u> , Vol. 327, pp. 293-297.
C7	Caetano-Anollés (1993) Amplifying DNA with Arbitrary Oligonucleotide Primers, <i>PCR Methods and Applications</i> , 3:85-94.
C8	Caldas, <i>et al.</i> , (1994) Detection of K-ras Mutations in the Stool of Patients with Pancreatic Adenocarcinoma and Pancreatic Ductal Hyperplasia, <i>Cancer Research</i> , 54:3568-3573.
C9	Capozzi <i>et al.</i> (1999) "Evaluation of the Replication Error Phenotype in Relation to Molecular and Clinicopathological Features in Hereditary and Early Onset Colorectal Cancer" <u>European Journal of Cancer</u> 35: 289-295
C10	Cave <i>et al.</i> , (1994) "Reliability of PCR Directly from Stool Samples: Usefulness of an Internal Standard," <u>BioTechniques</u> , Vol. 16, No. 5, pp. 809-810.
C11	Chapelle (1999) "Testing Tumors for Microsatellite Instability" <u>European Journal of Human Genetics</u> 7: 407-408
C12	Charlesworth <i>et al.</i> , (September 15, 1994) "The Evolutionary Dynamics of Repetitive DNA in Eukaryotes," <u>Nature</u> , Vol. 371, pp. 215-220.
C13	Chen <i>et al.</i> (1997) "Microsatellite Instability in Sporadic-Colon-Cancer Patients With and Without Liver Metastases" <u>International Journal of Cancer</u> 74: 470-474
C14	Chen <i>et al.</i> (1997) "Fluorescence Energy Transfer Detection as a Homogeneous DNA Diagnostic Method", <i>Proc. Natl. Acad. Sci. USA</i> , 94: 10756-10761
C15	Coll <i>et al.</i> , (October 1989) "Evaluation of a Rapid Method of Extracting DNA from Stool Samples for Use in Hybridization Assays," <u>Journal of Clinical Microbiology</u> , Vol. 27, No. 10, pp. 2245-2248.
C16	Coughlin <i>et al.</i> (1999) "Public Health Perspectives on Testing for Colorectal Cancer Susceptibility Genes" <u>American Journal of Preventive Medicine</u> 16: 99-104
C17	Cunningham C. and M.G. Dunlop, (1996) "Molecular Genetic Basis of Colorectal Cancer Susceptibility," <u>British Journal of Surgery</u> , Vol. 83, pp. 321-329.
C18	Deng <i>et al.</i> , (December 20, 1996) "Loss of Heterozygosity in Normal Tissue Adjacent to Breast Carcinomas," <u>Science</u> , Vol. 274, pp. 2057-2059.
C19	Deuter <i>et al.</i> , (1995) "A Method for Preparation of Fecal DNA Suitable for PCR," <u>Nucleic Acids Research</u> , Vol. 23, No. 18, pp. 3800-3801.
C20	Dib <i>et al.</i> , (March 14, 1996) "A Comprehensive Genetic Map of the Human Genome Based on 5,264 Microsatellites," <u>Nature</u> Vol. 380, pp. 152-154.
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## OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C21	Duffy M.J., (1995) "Can Molecular Markers Now be Used for Early Diagnosis of Malignancy?" <u>Clin. Chem.</u> , Vol. 41, No.10, pp. 1410-1413.
	C22	Eguchi <i>et al.</i> , (April 15, 1996) "Mutations of the p53 Gene in the Stool of Patients with Resectable Colorectal Cancer," <u>Cancer Supplement</u> , Vol. 77, No. 8, pp. 1707-1710.
	C23	Enari <i>et al.</i> , (January 1, 1998) "A Caspase-Activated DNase that Degrades DNA During Apoptosis, and its Inhibitor ICAD," <u>Nature</u> , Vol. 391, pp. 43-50.
	C24	"Experimental Protocol", <u>Nature Biotechnology</u> , (August, 1999), Vol. 17, pg. 807
	C25	Fearon, E.R., (1995) "16 Molecular Abnormalities in Colon and Rectal Cancer," <u>The Molecular Basis of Cancer</u> , pp. 340-357.
	C26	Fu, <i>et al.</i> , (1995) A DNA Sequencing Strategy That Requires Only Five Bases of Known Terminal Sequence for Priming, <u>Proc. Natl. Acad. Sci. USA</u> , 92:10162-10166.
	C27	Grossman <i>et al.</i> (1988), "Colonoscopic Screening of persons With Suspected Risk Factors for Colon Cancer" <u>Gastroenterology</u> 94: 395-400
	C28	Gyllenstein U. B., Allen M., (1995) "Sequencing of In Vitro Amplified DNA," <u>Recombinant DNA Methodology II</u> , (Wu, ed.), pp. 565-578.
	C29	Hasegawa <i>et al.</i> , (1995) "Detection of K-ras Mutations in DNAs Isolated From Feces of Patients with Colorectal Tumors by Mutant-Allele-Specific Amplification (MASA)," <u>Oncogene</u> , Vol. 10, pp. 1441-1445.
	C30	Hoang <i>et al.</i> (1997) "BAT-26, an Indicator of the Replication Error Phenotype in Colorectal Cancers and Cell Lines" <u>Cancer Research</u> 57: 300-303
	C31	Honchel <i>et al.</i> , (1995) "Genomic Instability in Neoplasia," <u>Seminars in Cell Biology</u> , Vol. 6, pp. 45-52.
	C32	Hoss <i>et al.</i> , (September 17, 1992) "Excrement Analysis by PCR" <u>Scientific Correspondence</u> pp. 199.
	C33	Iino <i>et al.</i> (1999) "DNA Microsatellite Instability in Hyperplastic Polyps, Serrated Adenomas, and Mixed Polyps: a Mild Mutator Pathway for Colorectal Cancer?" <u>Journal of Clinical Pathology</u> 52: 5-9
	C34	Ikonen, <i>et al.</i> , (1992) Quantitative Determination of Rare mRNA Species by PCR and Solid-phase Minisequencing, <u>PCR Methods and Applications</u> 1:234-240.
	C35	Iniesta <i>et al.</i> (1998) "Genetic Abnormalities and Microsatellite Instability in Colorectal Cancer" <u>Cancer Detection and Prevention</u> 22: 383-395
	C36	Ishimaru <i>et al.</i> (1995) "Microsatellite Instability in Primary and Metastatic Colorectal Cancers" <u>Int. J. Cancer (Pred. Oncol.)</u> , 64: 153-157
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C37	Jarvinen <i>et al.</i> (1995) "Screening Reduces Colorectal Cancer Rate in Families With Hereditary Nonpolyposis Colorectal Cancer" <u>Gastroenterology</u> 108: 1405-1411.
C38	Jernvall <i>et al.</i> (1999) "Microsatellite Instability: Impact on Cancer Progression in Proximal and Distal Colorectal Cancers" <u>European Journal of Cancer</u> 35, No. 2, pp. 197-201.
C39	Jessup J.M. and G.E. Gallick, (September/October 1992) "The Biology of Colorectal Carcinoma," <u>Current Problems in Cancer</u> pp. 263-328.
C40	Jonsson <i>et al.</i> , (January 1995) "From Mutation Mapping to Phenotype Cloning," <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 92 pp. 83-85.
C41	Kieleczawa, <i>et al.</i> , (1992) DNA Sequencing by Primer Walking with Strings of Contiguous Hexamers, <u>Science</u> , 258:1787-1791.
C42	Kim <i>et al.</i> (1998) "Microsatellite Instability in Young Patients With Colorectal Cancer" <u>Pathology International</u> 48: 586-594
C43	Konishi <i>et al.</i> (1996) "Molecular Nature of Colon Tumors in Hereditary Nonpolyposis Colon Cancer, Familial Polyposis, and Sporadic Colon Cancer" <u>Gastroenterology</u> 111: 307-317
C44	Kotler, <i>et al.</i> , (1993) DNA Sequencing: Modular Primers Assembled from a Library of Hexamers or Pentamers, <u>Proc. Natl. Acad. Sci. USA</u> , 90:4241-4245.
C45	Krook, <i>et al.</i> , (1992) Rapid and simultaneous detection of multiple mutations by pooled and multiplex single nucleotide primer extension: application to the study of insulin-responsive glucose transporter and insulin reception in non-insulin-dependent diabetes, <u>Human Molecular Genetics</u> , 1:391-395.
C46	Lamberti <i>et al.</i> (1999) "Microsatellite Instability - a Useful Diagnostic Tool to Select Patients at High Risk for Hereditary Non-Polyposis Colorectal Cancer: A Study in Different Groups of Patients With Colorectal Cancer" <u>Gut</u> 44: 839-843
C47	Lebacqz, (1992) Polymerase chain reaction and other methods to detect hot-spot and multiple gene mutations, <u>Ann Biol Clin</u> , 50:709-712.
C48	Lengauer <i>et al.</i> , (December 17, 1998) "Genetic Instabilities in Human Cancers," <u>Nature</u> , Vol. 396, pp. 643-649.
C49	Leong <i>et al.</i> , (1993) "Detection of MYCN Gene Amplification and Deletions of Chromosome 1p in Neuroblastoma by In Situ Hybridization Using Routine Histologic Sections," <u>Laboratory Investigation</u> , Vol. 69, No. 1, pp. 43-50.
C50	Lin <i>et al.</i> (1998) "Colorectal and Extracolonic Cancer Variations in MLH1/MSH2 Hereditary Nonpolyposis Colorectal Cancer Kindreds and the General Population" <u>Diseases of the Colon &amp; Rectum</u> 41: 428-433
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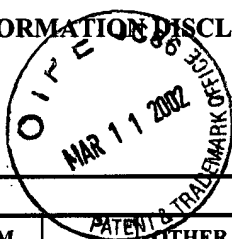
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	C79	Samowitz <i>et al.</i> (1997) "Microsatellite Instability in Colorectal Adenomas" <u>Gastroenterology</u> 112: 1515-1519
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C95	Vogelstein <i>et al.</i> (August, 1999) "Digital PCR," <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 96, pp. 9236-9241.
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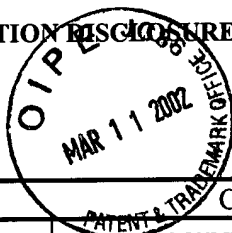
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C100	Wijnen <i>et al.</i> (1999) "Familial Endometrial Cancer in Female Carriers of MSH6 Germline Mutations," <u>Nature Genetics</u> 23: 142-144
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	C111	Schlegel <i>et al.</i> (1995) "Comparative Genomic in Situ Hybridization of Colon Carcinomas with Replication Error" <u>Cancer Research</u> , Vol. 55, pp. 6002-6005.
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